Washington State Institutional Review Board

REVIEW CONSIDERATIONS

The Washington State Institutional Review Board's primary function is to protect the rights and welfare of individuals who participate in research under its jurisdiction. The Review Board must determine that the proposed project design and methods are adequate and appropriate in the light of stated project purposes; that the rights and welfare of research participants are adequately protected; that participants are fully informed and provide consent voluntarily; and that risks to participants are minimized, are not unreasonable, and are outweighed by potential benefits to them or by the knowledge to be gained.

The Washington State Institutional Review Board is guided by federal regulations, the Belmont Report, institutional policies, and applicable state laws and regulations. The Washington State Agency Policy on Protection of Human Research Subjects is based on the federal regulation for the protection of human subjects (45 CFR 46), but it is somewhat more restrictive. For example some research which is exempt from review in federal regulation is subject to at least expedited review by the state agency policy. Review also must include assessment of local laws and regulations which may apply to the research activity. In Washington, such laws may include abuse reporting, mandatory disease reporting, disclosure of HIV testing or treatment of STDs, access to confidential medical information, and access to identifiable department records, among others. Copies of pertinent laws, codes and regulations are included in the Board Member Handbook for reference.

Board members are encouraged to use the *WSIRB Review Worksheet* for guidance in reviewing proposals. The following areas should be carefully considered during Review Board deliberations:

- **Scientific Merit**

The review of research begins with an assessment of the overall scientific merit and the logical and technical soundness of the proposal. The proposal should discuss the relevant literature or describe the context in which the study will occur to provide an adequate conceptual framework. The objectives, research questions and/or hypotheses of the study should be clearly stated, and the proposed methods and study instruments should produce data relevant to the study objectives. Plans for data analysis should be well-defined and likely to produce results related to the study purposes, objectives and hypotheses. The researcher should have appropriate qualifications to conduct the project, or adequate supervision by a qualified professional if the researcher is a student.

- **Study Population**

Research proposals should clearly define who will be enrolled as participants in the research and explain why these subjects are being selected. Justification for inclusion and exclusion criteria should be reviewed carefully to determine if subject selection is equitable and appropriate for study objectives. Classes of subjects should not be systematically included

or excluded for arbitrary reasons. Reviewers should consider whether participants will share benefits in proportion to burdens imposed by the research. If vulnerable populations are included, reviewers should consider whether the research could be done with a non-vulnerable population or whether additional safeguards are necessary to protect vulnerable subjects.

- **Subject Recruitment**

Reviewers should examine the procedures for identifying, contacting and recruiting potential subjects. Generally, researchers should not make first contact with potential subjects. If the researcher proposes to identify and sample the study population from confidential state agency records, contact must first be made by agency employees and individuals must be provided, at a minimum, the option of refusing further contact regarding the research. Recruitment procedures and materials should provide information in terms that the intended population can understand and should be free of coercion.

- **Informed Consent**

The informed consent process must ensure 1) adequate information, 2) comprehension and 3) voluntary participation. Reviewers should consider the appropriateness of the individual(s) who will obtain consent, as well as the location and timing of the consent process. The researcher must provide complete information about the proposed research and the individual's role in the research in terms that the potential subject can understand and in an environment and manner that is free of coercion or undue influence. Consent/assent documents must contain all required consent elements, and be written in appropriate reading levels and languages for the intended populations.

Research proposals involving vulnerable populations (including pregnant women, fetuses, children, decisionally impaired, institutionalized, prisoners, socially or economically disadvantaged) merit special consideration to determine whether subjects are capable of understanding the research and providing informed consent, and to minimize the potential for coercion in the consent process. The Review Board must ensure that there are adequate safeguards in place to protect the interests of vulnerable subjects, i.e., requiring a consent witness or subject advocate. Assent to participate in research generally is required from persons who are decisionally impaired and/or legally incompetent, as well as children less than 18 years of age. In addition, informed consent generally must be obtained from parents or legal guardians, family members who may legally provide consent, and, in some cases, a social worker of these potential subjects.

Waivers or alterations of consent requirements may be approved by the Review Board provided the conditions delineated in 45 CFR 46 have been documented to the Board's satisfaction.

Confidentiality

Board members should carefully consider possible risks to participant confidentiality in all phases of the proposed research: sampling, recruitment, consent procedures, proposed methods and setting for data collection, etc. The Board may require alterations in the

proposed study to minimize confidentiality risks. Research which may pose special confidentiality concerns involve instruments which collect sensitive information regarding the individual's behavior or experiences, genetics research, retention of research information in program or client records, and illegal behaviors, to name a few.

- **Benefits and Risks**

A fundamental task in the Board's review of proposals is to balance the anticipated benefits and risks of the research activity. Benefits accruing from research may include direct, personal benefits to the participants, such as the provision of a new therapeutic procedure or drug, or the opportunity to obtain services not otherwise available. Benefits also include general societal benefits in the form of new scientific or applied knowledge. Risks include any research activities that potentially may harm the research participant: psychologically, physically, socially, economically, legally, or otherwise. Risks may range from physical injury from biomedical or pharmaceutical research, to mere inconvenience from participation in survey research. In assessing risks inherent in a proposal, reviewers should consider both the magnitude and probability of the harm occurring. If the balance between risks and benefits is unfavorable, the Review Board should explore options for reducing risks and/or increasing benefits.

- **Review Disposition**

Assuming all regulatory requirements have been met, the Review Board determines the final review disposition by balancing the risks to subjects in relation to anticipated benefits to the subjects and/or society. If the risks are outweighed by the anticipated benefits, the proposal may be approved or conditionally approved subject to clarifications and/or revisions in procedures. If insufficient information exists for the Board to clearly determine the risks and/or anticipated benefits of the research, the proposal may be held in abeyance pending submission of necessary information. If risks clearly outweigh anticipated benefits, and it is not possible to increase benefits or reduce risks, the proposal may be disapproved. The Review Board does not disapprove a proposal until the researcher has been given an opportunity to address issues and concerns raised by the Board.

Proposals reviewed by the Washington State Institutional Review Board encompass a wide range of scientific and social inquiry. While no individual has expertise in all fields, members are chosen to ensure that as many areas of inquiry as possible are represented on the Board. The Executive Secretary and Associate Executive Secretary are available to provide consultation during the review process. Board members are encouraged to raise questions and discuss issues with Review Section staff (as well as with other Board members) who will provide guidance, resource materials, and referral to other sources of information and expertise.